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Richard Wilson,

Acting Assistant Administrator, Office of Air and Radiation.

[FR Doc. 95–18834 Filed 7–31–95; 8:45 am]

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40 CFR Part 372

[OPPTS–400095; FRL–4958–8]

Di-(2-ethylhexyl) Adipate; Toxic Chemical Release Reporting; Community Right-to-Know

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to grant a petition to delist di-(2-ethylhexyl) adipate (DEHA) (Chemical Abstract Service (CAS) No. 103-23-1), also known as bis-(2-ethylhexyl) adipate, from the reporting requirements under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and section 6607 of the Pollution Prevention Act of 1990 (PPA). This action is based on EPA's preliminary conclusion that DEHA meets the deletion criteria of EPCRA section 313(d)(3). Specifically, EPA is proposing to grant this petition because, based on the total weight of available data, EPA believes that: (1) DEHA cannot reasonably be anticipated to cause significant acute adverse human health effects at concentration levels expected to occur beyond facility site boundaries and thus does not meet the criterion of EPCRA section 313(d)(2)(A); (2) DEHA does not meet the criterion of EPCRA section 313(d)(2)(B) because it cannot reasonably be anticipated to cause cancer, teratogenic effects, immunotoxicity, neurotoxicity, gene mutations, liver, kidney, reproductive, or developmental toxicity or other serious or irreversible chronic health effects; and (3) DEHA does not meet the criterion of EPCRA section 313(d)(2)(C) because it cannot reasonably be anticipated to cause significant and serious adverse effects on the environment.

DATES: Written comments on this proposed rule must be received by October 2, 1995.

ADDRESSES: Submit written comments in triplicate and identified with docket number ''OPPTS–400095'' to: OPPT Document Control Officer (7407), Environmental Protection Agency, Rm. NE–G99, 401 M St., SW., Washington, DC 20460.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number OPPTS–400095. No CBI should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in Unit V. of this document.

FOR FURTHER INFORMATION CONTACT: Maria J. Doa, 202-260-9592, e-mail: doa.maria@epamail.epa.gov, for specific information regarding this proposed rule. For further information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Information Hotline, Environmental Protection Agency, Mail Stop 5101, 401 M St., SW., Washington, DC 20460, Toll free: 800-535-0202, in Virginia and Alaska: 703-412-9877, or Toll free TDD: 800-553-7672.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Authority

This action is taken under sections 313(d) and (e)(1) of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), 42 U.S.C. 11023. EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 (Pub. L. 99-499).

B. Background

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using listed toxic chemicals to report their environmental releases of such chemicals annually. Beginning with the 1991 reporting year, such facilities also must report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the Pollution Prevention Act of 1990 (PPA), 42 U.S.C. 13106. Section 313 of EPCRA established an initial list of toxic chemicals that was comprised of more than 300 chemicals and 20 chemical categories. DEHA was included in the initial list of chemicals and categories. Section 313(d) authorizes EPA to add or delete chemicals from the list, and sets forth criteria for these actions. EPA has added and deleted chemicals from the original statutory list. Under section 313(e), any person may petition EPA to add chemicals to or delete chemicals from the list. EPA must respond to petitions within 180 days, either by initiating a rulemaking or by publishing an explanation of why the petition is denied.

EPA issued a statement of petition policy and guidance in the **Federal Register** of February 4, 1987 (52 FR 3479), to provide guidance regarding the recommended content and format for submitting petitions. On May 23, 1991 (56 FR 23703), EPA issued guidance regarding the recommended content of petitions to delete individual members of the section 313 metal compound categories. EPA has also published a statement clarifying its interpretation of the section 313(d)(2) and (3) criteria for adding and deleting chemical substances from the section 313 list (59 FR 61439, November 30, 1994).

II. Description of Petition and Other Applicable Regulations

On January 18, 1995, EPA received a petition from the Chemical Manufacturers Association to exclude di-(2-ethylhexyl) adipate (DEHA) from section 313 of EPCRA. Specifically, the petition requests that DEHA be deleted from the list of reportable chemicals and not be subject to the annual reporting requirements under EPCRA section 313 and section 6607 of the PPA. The petitioner contends that DEHA should be deleted from the EPCRA section 313 list because, in their opinion, the available data show that DEHA does not meet the criteria for inclusion on the list of EPCRA section 313 chemicals.

Under the Safe Drinking Water Act, DEHA has a Maximum Contaminant Level of 0.4 milligrams per liter (mg/L).

III. EPA's Technical Review of Di-(2-ethylhexyl) adipate

A. Chemistry

DEHA (CAS No. 103-23-1), also known as bis(2-ethylhexyl) adipate and as dioctyl adipate, is an aliphatic ester used primarily as a plasticizer in a variety of products such as polyvinyl chloride (PVC) and other plastics, cellophane, rubber, and cosmetics. It is a light-colored, oily liquid with low water solubility (0.78 milligrams/liter (mg/L) at 22 °C measured in 1986). DEHA has a very high boiling point (410 °C), low volatility, very low pour point, and excellent low temperature fluidity (Ref. 1).

B. Toxicological Evaluation

Information on DEHA was reviewed for evidence indicating: (1) Bioavailability and metabolism; (2) acute toxicity; (3) chronic toxicity; (4) carcinogenicity; and (5) ecotoxicity.

1. *Bioavailability and metabolism*. DEHA is well absorbed from the gastrointestinal tract of rats, mice, monkeys, and humans (Ref. 2). No data were available concerning the possible absorption of DEHA from the lung or through the skin.

DEHA is rapidly hydrolyzed to adipic acid and 2-ethylhexanol both *in vivo* and *in vitro*. 2-Ethylhexanol is subsequently metabolized to ethylhexanoic acid and other acid and hydroxy acid derivatives and their gluconuride conjugates. Adipic acid is further oxidized to carbon dioxide. Excretion is primarily in the urine, with smaller amounts excreted in the expired air (carbon dioxide) and feces (Ref. 2).

2. *Acute toxicity*. DEHA exhibits slight acute toxicity. The oral median Lethal Dose (LD_{50}) value for rats is greater than 8 grams per kilogram (g/kg), and the dermal LD_{50} value for rabbits is greater than 9 g/kg (Ref. 2). There was no mortality among rats exposed by inhalation to a saturated vapor. DEHA was not irritating to rabbit eyes and skin, and it was not a dermal sensitizer in guinea pigs.

3. *Chronic toxicity*. Several chronic and subchronic feeding studies in rats and mice show that DEHA is not highly toxic. The primary effect in both species appears to be body weight depression. In rats, the Lowest Observed Adverse Effect Level (LOAEL) was 1,125 milligrams per kilogram per day (mg/kg/day) for both the chronic and 13-week studies. In mice, the LOAELs ranged from 2,800 mg/kg/day (chronic study) to 900 mg/kg/day (13-week study) (Ref. 2).

The weight of the evidence from several mutagenicity assays indicates that DEHA is probably not mutagenic (Ref. 2). Although most mutagenicity assays on DEHA are negative, DEHA does produce chromosome mutations in mammalian cells in culture (weakly), increase DNA synthesis in rats *in vivo*, and induce dominant lethals in mice *in vivo*. A positive response in the dominant lethal without collaborating genotoxicity data in assay systems designed to assess basic mutagenicity hazard is not an indication of potential mutagenicity (Ref. 2).

Data on both developmental and reproductive system toxicity are limited (Ref. 2). For developmental toxicity, a standard protocol test is available for only one species. For reproductive toxicity, there is a one-generation test, but not a multi-generation test. The one-generation reproduction study on male and female rats showed a reduction in litter size with administration of approximately 1,080 mg/kg/day of DEHA in feed, but the reduction was small and not statistically significant. The dominant-lethal assay discussed above found a dose-related increase in early fetal death, but the increase was not statistically significant and doses (0.46 to 9.2 g/kg, by single interperitoneal injection) were high.

4. *Carcinogenicity*. The National Toxicology Program tested DEHA for carcinogenicity in male and female rats and mice treated via diet (Ref. 2). Doses were approximately 700 or 1,500 mg/kg/day in the rat and 2,800 or 7,000 mg/kg/day in the mouse. The chemical was carcinogenic for female mice, inducing a significantly increased incidence of hepatocellular carcinomas. A marginally significant increase in hepatocellular carcinomas and adenomas combined was reported for male mice as compared with that of the concurrent controls. DEHA was not carcinogenic for the rats of either sex.

5. *Ecotoxicity*. DEHA is not expected to pose a significant hazard to the environment. Based on structure activity relationships (SARs), no toxic effects are anticipated for both freshwater and saltwater species at saturation (Ref. 2). For sediment species, acute and chronic toxicity are expected to occur only at high concentrations: 1,000 and 100 mg/kg (dry weight), respectively.

C. Environmental Fate

DEHA released to air has an estimated half-life for hydroxy radical oxidation of 5.2 hours. No information was found on photolysis of DEHA in air.

DEHA released to water is expected to undergo biodegradation in the water column with a half-life on the order of days to weeks. It will also partition readily to sediment based on its estimated soil organic carbon partition coefficient of 15,500. Once bound to sediments, DEHA will probably continue to biodegrade, but possibly at a significantly slower rate (halflife on the order of months). Hydrolysis is not expected to be a significant removal process below pH 9 (estimated half-life = 3.2 years at pH 7).

DEHA released to soil is expected to adsorb strongly based on its estimated soil organic carbon partition coefficient (15,500). Biodegradation is possible, and could further mitigate migration through soil. Biodegradation half-life in soils is estimated on the order of weeks.

DEHA is expected to be removed from wastewater in biological wastewater treatment systems by adsorption and biodegradation. Based on available biodegradation data and physical chemistry properties, 90 percent removal in Publicly Owned Treatment Works was estimated.

D. Exposure and Releases

Reported releases of DEHA were retrieved from the Toxic Release Inventory System (TRIS) and used to estimate air and water concentrations using TRIAIR and TRIWATER modeling techniques. The estimated maximum Lifetime Average Daily Potential Dose via inhalation (0.00178 mg/kg/day) is over 300-fold less than the Reference Dose (RfD) (0.6 mg/kg/day). The difference for oral exposure is much greater for water (Ref. 3). Based on this information, releases of DEHA are not expected to result in exposures of concern for human health or the environment.

The Agency believes that exposure considerations are appropriate in making determinations: (1) Under section 313(d)(2)(A); (2) under section 313(d)(2)(B) for chemicals that exhibit low to moderately low toxicity based on a hazard assessment; and (3) under section 313(d)(2)(C) for chemicals that are low or moderately ecotoxic but do not induce well-documented serious adverse effects. The Agency believes that exposure considerations are not appropriate in making determinations: (1) Under section 313(d)(2)(B) for chemicals that exhibit moderately high to high human toxicity based on a hazard assessment; and (2) under section 313(d)(2)(C) for chemicals that are highly ecotoxic or induce well-established adverse environmental effects. Given DEHA's low chronic toxicity and low ecotoxicity, exposure considerations are appropriate for detrminations under sections 313(d)(2)(B) and (C) as part of this proposed rule to delist. A more detailed discussion of EPA's listing determination guidelines is provided in the **Federal Register** of November 30, 1994 (59 FR 61442).

E. Technical Summary

Based on the total weight of available toxicity data, EPA believes that DEHA cannot reasonably be anticipated to cause significant adverse effects on human health or the environment. DEHA exhibits slight acute toxicity and causes adverse chronic effects only at high doses. Furthermore, DEHA is not expected to pose a significant hazard to the environment. In addition, based on EPA's exposure assessment, releases of DEHA are not expected to result in exposures of concern.

IV. Rationale for Proposal to Grant

EPA is granting the petition by proposing to delete DEHA from the EPCRA section 313 list of toxic chemicals. This decision is based on the

Agency's preliminary determination that DEHA does not meet the toxicity criterion of EPCRA section 313(d)(2)(A) because it cannot reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.

EPA has preliminarily concluded that DEHA does not meet the criterion of EPCRA section 313(d)(2)(B) because it cannot reasonably be anticipated to cause teratogenic effects, immunotoxicity, neurotoxicity, or liver, kidney, reproductive, or developmental toxicity or other serious or irreversible chronic health effects. Furthermore, while EPA has classified DEHA as a Group C, possible human carcinogen, clear evidence of carcinogenicity was observed in only one species-sex group (mice-female) in the animal studies. EPA believes that there is a lack of clear evidence of possible carcinogenicity in male mice. Therefore, EPA believes that, overall, the evidence is too limited to establish that DEHA is likely to cause cancer. EPA believes that DEHA has low chronic toxicity and accordingly has considered exposure factors. As stated above, EPA has concluded that anticipated exposure concentrations of DEHA are not expected to result in significant adverse effects. Therefore, EPA has preliminarily concluded that DEHA does not meet the EPCRA section 313(d)(2)(B) listing criterion.

EPA has also preliminarily determined that DEHA does not meet the toxicity criterion of EPCRA section 313(d)(2)(C) because it cannot reasonably be anticipated to cause adverse effects on the environment of sufficient seriousness to warrant continued reporting.

Thus, in accordance with EPCRA section 313(d)(3), EPA is proposing to delete DEHA from the section 313 list of toxic chemicals.

V. Rulemaking Record

A record has been established for this proposed rule under docket number ''OPPTS–400095'' (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as confidential business information (CBI), is available for inspection from noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in the TSCA Nonconfidential Information Center, Rm. NE-B607, 401 M St., SW., Washington, DC 20460.

Electronic comments can be sent directly to EPA at:
ncic@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

VI. References

(1) USEPA, OPPT, EETD. Jenny Tou, ''Chemistry Report on Di(2-ethylhexyl) Adipate,'' dated April 27, 1995.

(2) USEPA, OPPT, CSRAD. Memorandum from Lorraine Randecker to Fred Metz, entitled ''Petition to Delist Di(2-ethylhexyl) Adipate,'' dated May 22, 1995.

(3) USEPA, OPPT, EETD. David Lynch, ''Exposure Assessment for DEHA in Response to Delisting Petition,'' dated March 21, 1995.

VII. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Pursuant to the terms of this Executive Order, it has been determined that this proposed rule is not ''significant'' and therefore not subject to OMB review.

EPA estimates that the reduction in costs to industry associated with the deletion of DEHA would be approximately $322,620. The costs savings to EPA are estimated at $8,664, if DEHA is deleted from the EPCRA section 313 list.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980, the Agency must conduct a small business analysis to determine whether a substantial number of small entities would be significantly affected by the rule. Because this proposed rule eliminates an existing requirement, it would result in cost savings to facilities, including small entities.

C. Paperwork Reduction Act

This proposed rule does not have any information collection requirements subject to the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

D. Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995, which the President signed into law on March 22, 1995, EPA has assessed the effects of this regulatory action on State, local or tribal governments, and the private sector. This action does not result in the expenditure of $100 million or more by any State, local or tribal governments, or by anyone in the private sector. The costs associated with this action are described in the Executive Order 12866 unit above.

List of Subjects in 40 CFR Part 372

Environmental protection, Chemicals, Community Right-to-Know, Reporting and recordkeeping requirements, Toxic chemicals.

Dated: July 24, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR part 372 is amended as follows:

1. The authority citation for part 372 would continue to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

§ 372.65 [Amended]

2. Sections 372.65(a) and (b) are amended by deleting the entry for Bis(2-ethylhexyl) adipate under paragraph (a) and the entire CAS number entry for 103-23-1 under paragraph (b).

[FR Doc. 95–18870 Filed 7–31–95; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR PART 1

[MM Docket No. 95–110; FCC 95–277]

Broadcast Services; Allocations; Automatic Stay

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rule making.

SUMMARY: This Notice of Proposed Rule Making proposes to delete the automatic stay provision in Section 1.420(f) of the Commission's rules. That rule applies to proposals to amend the FM and TV Tables of Allotments and provides for